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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,951

04/20/2006

Brian Anderton

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1601 MARKET STREET
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PHILADELPHIA, PA 19103-2307

EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,951	Applicant(s) ANDERTON ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-46 and 50-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-46 and 50-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 22-46 and 50-54 are pending in the application.
- [2] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 9/24/07, is acknowledged. *In order to perfect the requirements for a sequence listing, applicant is required to submit an amendment directing entry of the substitute sequence listing paper copy into the specification.*
- [3] Solely for purposes of grouping the claims for the instant lack of unity, claim 54 has been interpreted as being dependent upon claim 53, not claim 51.

Lack of Unity

- [4] Applicant's election with traverse of Group I, original claims 22-32, 36, and 38-42, and SEQ ID NO:1 in the reply filed on 6/22/07 is acknowledged.
- [5] Upon reconsideration of the lack of unity in the Office communication filed on 4/24/07, the following is a supplemental lack of unity requirement.
- [6] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Group I, claim(s) 22-36, 38-42, 51, drawn to a method of screening for inhibitors of Tau protein phosphorylation by a kinase including CK1 using a combination of kinases.

Group II, claim(s) 22-32, 36-42, 51, drawn to a method of screening for inhibitors of Tau protein phosphorylation by a kinase including CK1 using a substrate other than Tau protein.

Group III, claim(s) 22-32, 36, 38-45, 51, drawn to a method of screening for inhibitors of Tau protein phosphorylation by a kinase including CK1 and further optimizing the structure of the candidate substance and preparing a pharmaceutical composition.

Group IV, claim(s) 46, drawn to a substance obtained by a method of screening for inhibitors of Tau protein phosphorylation by CK1.

Group V, claim(s) 50-51, drawn to a method of screening for inhibitors of Tau phosphorylation by a kinase including Fyn.

Group VI, Claim 52, a method of screening for substances capable of promoting dephosphorylation of Tau by a phosphatase.

Group VII, claims 53-54, a method of treatment of taupathy.

[7] The technical feature linking the inventions of Groups I-VII is a method of screening for substances that inhibit tau phosphorylation by CKI. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The inventions of Groups I-VII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Groups I-VII is a method of screening for substances that inhibit tau phosphorylation by CKI, which is shown by Kuret et al. (*J. Neurochem.* 69:2506-2515, 1997; cited in the IDS filed on 4/20/06) to lack novelty or inventive step because the reference of Kuret et al. teaches CKI phosphorylates tau, has cell cycle-dependent association with microtubules, and has tight association with tau pathology, and that properties of CKI-alpha isoforms are favorable for playing a role in the formation of hyperphosphorylated tau in neurodegenerative disease (p. 2513, column 2, bottom) and does not make it a contribution over the prior art. Moreover, Singh et al. (*Mol. Cell. Chem.* 131:181-189,

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1994) teaches that combinations of CK1 along with other kinases result in tau phosphorylation (p. 185, left column).

[8] This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of tau phosphorylation sites of claim 30 and 52 are as follows:

(a)	(S46/T50)	(b)	S113	(c)	S131
(d)	T149	(e)	T169	(f)	S184
(g)	S208	(h)	(S210/T212)	(i)	S214
(j)	S237	(k)	S238	(l)	S241
(m)	S258	(n)	S262	(o)	T263
(p)	S285	(q)	S289	(r)	S305
(t)	S341	(u)	S352	(v)	S356
(w)	T361	(x)	T373	(y)	T386
(z)	(S412/S413/T414)	(aa)	S416	(bb)	S433
(cc)	S435	(dd)	S68	(ee)	T69
(ff)	T71	(gg)	(T111/S113)	(hh)	S191
(ii)	S258	(jj)	S289	(kk)	(T414/S416)
(ll)	T427	(mm)	S433	(nn)	S435
(oo)	Y394				

[9] The technical feature linking species (a) to (oo) is a method of screening for inhibitors of tau phosphorylation by a kinase including CK1. The inventions listed as species (a) to (oo) do not relate to a single general inventive concept under PCT Rule

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13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure or property. Although the species (a) to (oo) are tau phosphorylation sites, the phosphorylation sites are not regarded as being of similar nature because each of the alternatives is a distinct amino acid position of Tau.

[10] This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of detecting phosphorylation of claim 39 are as follows:

- (i) mass spectroscopy
- (ii) site-specific recognition agent

[11] The technical feature linking species (i) to (ii) is a method of screening for inhibitors of tau phosphorylation by a kinase including CK1. The inventions listed as species (i) to (ii) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property. Although the species (i) and (ii) are methods for detecting phosphorylation, the methods do not share a common property and these methods are well-known as methods for detecting phosphorylation of a substrate.

[12] Applicant is required, in reply to this action, to elect a single species of tau phosphorylation site AND a single species of phosphorylation detection method to which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

[13] Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

[14] Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

[15] The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

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[16] Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

[17] Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

[18] The claims will be examined only to the extent they read on the elected subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
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